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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,601	05/04/2006	Bernard Piere Dominique Carcy	I-2003.005 US	8856

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EXAMINER	
ARCHIE, NINA	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,601	CARCY ET AL.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/16/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *3,6 and 16-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-5, 7-15, and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office is responsive to Applicant's amendment and response filed 4-16-08. Claims 1-2, and 19 have been amended. Claims 3, 6, and 16-18 have been withdrawn.

Rejections Withdrawn

2. In view of the Applicant's amendment and remark following objections are withdrawn.

a) Rejection to claim 19 under 35 USC 102(b), is withdrawn in light of applicant's amendment there.

b) Rejection to claims 1, 2, 4-5 and 7-10 under 35 U.S.C. § 112, first paragraph, is withdrawn in light of applicant's amendment there.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 4-5, 7, and 10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claimed invention is drawn to a product of nature. Products of nature are not patentable because they do not reflect the "hand of man" in the production of the product or manufacturing process. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Additionally, purity of naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui 156 USPQ 426 (1966). However when purity results in new utility, patentability is considered. Merck co. V. Chase Chemical Co. 273 F. Supp 68 (1967). See also American Wood v. Fiber Disintegrating Co., 90 US 566 (1974);American Fruit Growers v. Brogdex Co. 283 US 1 (1931); Funk Brothers Seed

Co. V. Kalo Innoculant Co. 33 US 127 (1948). In the instant case recitation of a nucleic acid that encodes the sequence and host cell does not indicate the hand of man because nucleic acids are naturally occurring, therefore the claimed nucleic acid and host cell are deemed products of nature.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 11-15 are rejected under 35 U.5.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contain subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained for the reasons set forth in the previous office action.

Applicant arguments:

Rejection of Claims 11-15 Under 35 U.S.C. § 112, First Paragraph
The Examiner has rejected claims 11-15 under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the enablement requirement. Office Action, page 3. Solely to expedite prosecution and not in acquiescence to the rejection, Applicants have amended claim 1 and it is now believed that this rejection is moot. Accordingly, Applicants request that the Examiner reconsider and withdraw the rejection.

Examiner's Response to Applicant's Arguments:

Although Applicant has amended claims this is not deemed persuasive. The specification is not enabled for any vaccine comprising an amino acid sequence, wherein said sequence provides prophylactic or therapeutic treatment of an infection or

its clinical signs caused by an organism of the family Babesiidae as discussed in the previous office action.

As outlined previously, the specification is not enabled for vaccine comprising an isolated amino acid sequence from 17 to 180 of SEQ ID NO: 2, wherein said sequence provides prophylactic or therapeutic treatment of an infection or its clinical signs caused by an organism of the family Babesiidae.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims. The claim is drawn to vaccine comprising an isolated amino acid sequence from 17 to 180 of SEQ ID NO: 2 being used for prophylactic or therapeutic treatment of an infection or its clinical signs caused by an organism of the family Babesiidae and are overly broad. Therefore it is hard for one skilled in the art to determine if a vaccine isolated amino acid sequence from 17 to 180 of SEQ ID NO: 2, wherein said sequence provides prophylactic or therapeutic treatment of an infection or its clinical signs caused by an organism of the family Babesiidae. The quantity of

experimentation required to practice the invention as claimed would require in vivo and in vitro studies of an isolated amino acid sequence from 17 to 180 of SEQ ID NO: 2, wherein said sequence provides prophylactic or therapeutic treatment of an infection or its clinical signs caused by an organism of the family Babesiidae. Since the specification fails to provide particular guidance for a isolated amino acid sequence from 17 to 180 of SEQ ID NO: 2, wherein said sequence provides prophylactic or therapeutic treatment of an infection or its clinical signs caused by an organism of the family Babesiidae for the particularly claimed conditions, it would require undue experimentation to practice the invention over the broad scope as presently claimed.

Nature of the invention. The claims are drawn to a vaccine comprising isolated amino acid sequence from 17 to 180 of SEQ ID NO: 2, wherein said sequence provides prophylactic or therapeutic treatment of an infection or its clinical signs caused by an organism of the family Babesiidae. The specification discloses in Example 3 (see pp. 48), vaccinations with Bc28.1 and Bc28.2 protein subunit vaccine.

The state of the prior art. The state of the art indicate as set forth by Plotkin et al (VACCINES W.B. Saunders Company, 1988, page 571) "The key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies... and thus protect the host against attack by the pathogen." This teaching directly addresses whether any isolated amino acid sequence, wherein said sequence provides prophylactic or therapeutic treatment of an infection or its clinical signs caused by an organism of the family Babesiidae. Furthermore, A vaccine "must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." In re Wright, 999 F.2d 1557,1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). The state of the art indicate that any substitution, insertion or deletion or change in an amino acid sequence or nucleic acid that encodes an amino acid highly complex and unpredictable. As taught by the prior art that even a single amino acid change in a protein leads to unpredictable changes in the biological activity of the protein. For

example, replacement of a single lysine residue at position 118 of the acidic fibroblast growth factor by glutamic acid led to a substantial loss of heparin binding, receptor binding, and biological-activity of the protein (Burgess et al., The Journal of Cell Biology, 111:2129-2138, 1990). Thus, it is apparent that change in a peptide leads to loss of binding property of that peptide. Furthermore, it is unclear whether the amino acid can be used for prophylactic or therapeutic treatment of an infection or its clinical signs caused by an organism of the family Babesiidae. It is known for nucleic acids as well as proteins, for example, that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. The effect of these changes are largely unpredictable as to which one have significant effect versus not. Therefore, the citation of sequence similarity results in an unpredictable and therefore unreliable correspondence between the claimed biomolecule and the indicated similar biomolecule of known function and therefore lacks support regarding utility and/or enablement. Bowie et al teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function, carry out the instructions of the genome and form immunoepitopes. Bowie et al. further teach that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. (column 1, page 1306). Bowie et al further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (column 2, page 1306). Several publications document this unpredictability of the relationship between sequence and function, albeit that certain specific sequence may be found to be conserved over biomolecules of related function upon a significant amount of further research. See the following publications that support this unpredictability as noting certain conserved

sequences in limited specific cases: (Gerhold et al [BioEssays, Vol.18, pages. 973-981 {1996}] Bowie et al (Science, 1990, 247:1306-1310). For the reasons set forth supra, the state of the art is unpredictable of any isolated amino acid sequence, wherein said sequence provides prophylactic or therapeutic treatment of an infection or its clinical signs caused by an organism of the family Babesiidae.

Guidance in the specification/Working Examples. The specification fails to provide an enabling disclosure for a vaccine isolated amino acid sequence from 17 to 180 of SEQ ID NO: 2, wherein said sequence provides prophylactic or therapeutic treatment of an infection or its clinical signs caused by an organism of the family Babesiidae. The specification provides no disclosure how any isolated amino acid, may be used as a vaccine because it fails to provide guidance whether this variant has the ability to induce a protective immune response or to bind to antisera from infected animal. Absent such demonstration, the invention would require undue experimentation to practice as claimed. The specification, however, provides no working examples demonstrating (i.e., guidance) enablement for vaccine, an isolated amino acid sequence from 17 to 180 of SEQ ID NO: 2, wherein said sequence provides prophylactic or therapeutic treatment of an infection or its clinical signs caused by an organism of the family Babesiidae.

In conclusion, the claimed inventions are not enabled for a vaccine isolated amino acid sequence from 17 to 180 of SEQ ID NO: 2, wherein said sequence provides prophylactic or therapeutic treatment of an infection or its clinical signs caused by an organism of the family Babesiidae. The specification discloses in Example 3 (see pp. 48), vaccinations with Bc28.1 and Bc28.2 protein subunit vaccine. The state of the art indicate that any substitution, insertion or deletion or change in an amino acid sequence or nucleic acid that encodes an amino acid highly complex and unpredictable. There is a lack of working examples. As a result, for the reasons discussed above, it would require undue experimentation for one skilled in the art to use the claimed invention.

Claim Rejections- 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Vettore et al 2001 Genet. Mol. Biol. Vol. 24 (1-4), (1-7).

Claim 19 is drawn to a diagnostic test for the detection of a nucleic acid associated with an organism of the family Babesiidae, comprising a nucleic acid sequence selected from the group consisting of: (i) SEQ ID NO: 1 or; (ii) a fragment of SEQ ID NO: 1 at least 15 nucleotides long; and (v) a nucleic acid that is complementary to any of (i) through (ii).

5. Vettore et al teach (ii) a fragment of SEQ ID NO: 1 at least 15 nucleotides long (see STIC Results). Thus Vettore et al teach an diagnostic test for the detection of a nucleic acid associated with an organism of the family Babesiidae, comprising a (ii) a fragment of SEQ ID NO: 1 at least 15 nucleotides long.

Status of the Claims

6. No claims are allowed.

Claims 1 (SEQ ID NO: 2) and claims 4-5, 7-15, and 19 are rejected.

Claims 20-21 are objected to as being dependent from a rejected base claim.

7. ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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